

REMARKS

Claims 1 and 6 have been amended to recite "extracted from" rather than "derived from." Thus, Claims 1, 2 and 5-7 remain pending in the present application. Support for the claim amendments may be found throughout the specification, for example at pages 18 and 19. No new matter has been added. Reconsideration and withdrawal of the present rejections in view of the comments presented herein are respectfully requested.

Evidence provided with response filed on July 1, 2009

In the Advisory Action, the Examiner stated that the evidence filed after the final action would not be entered. Applicants respectfully request consideration of this evidence, in addition to the remarks presented herein.

Rejection under 35 U.S.C. § 103(a)

The rejection of Claims 1, 2 and 5-7 as allegedly being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* 46:3875-3878, 1998) and Xia (CN1435125; Derwent Acc No 2004-023802) in view of Suzuki et al. (*J. Agric. Food Chem.* 48:5649-5653, 2000) and in further view of Iwasaki et al. (US 7,014,876) was maintained.

The pending claims recite a method of reduction of triglyceride levels by administering a functional beverage (claim 1) or composition (claim 6) comprising the recited methylated catechins and extracted from the recited list of tea leaves. The present invention relates, in part, to Applicants' discovery that methylated catechins are unexpectedly much better than non-methylated catechins at reducing triglyceride (TG) levels. Based on this unexpected discovery, they identified the varieties of tea listed in Claims 1 and 6 that have high levels of methylated catechins, and selected these teas for reducing triglyceride levels. Nothing in the prior art would lead one of ordinary skill in the art to select the presently claimed types of teas.

a. Unexpected Results

The unexpected results obtained by Applicants' invention were reported both in Applicants' specification and in the Partial Translation of Reference Documents 1 and 2 submitted with Applicant's previous response. Specifically, the specification discloses in Example 3 on pages 24-25 that a test group given a beverage high in methyl catechins derived from "Benifuuki" tea had dramatically lowered triglyceride levels compared to a control group given a beverage low in methyl catechins derived from Barley tea. Although Barley tea is low in methyl catechins, barley tea is

known to contain significant levels of catechins. See the attached abstract of Baik, J. Ag. Food Chem. 54:9978-9984 (2006) obtained at <http://cat.inist.fr/?aModele=afficheN&cpsidt=18368307>. Thus, an unexpectedly higher level of TG reduction was found in the group given a tea high in methyl catechins compared to the group given tea low in methyl catechins.

Moreover, Reference Document 1 reports similar results when a high methyl catechin tea, such as "Benifuuki" is compared with a low methyl catechin tea, such as "Yabukita." Table 1 of Reference Document 1 reports the results for a number of parameters in the two different groups, including "neutral fat," which is another term for triglycerides. A control group not receiving any additive had an average neutral fat level of 61.5 mg/dL. The "Yabukita" group had virtually the same neutral fat level at 61.2 mg/dL. In contrast, the "Benifuuki" group, had a more than 20% reduction, at 50.0 mg/dL.

Based on the discovery that teas high in methyl catechins have a significant TG-lowering effect, while teas low in methyl catechins have little effect on TG, Applicants identified the recited varieties of teas as those having high levels of methyl catechins. These particular teas have unexpectedly high levels of TG-lowering effect. As nothing in the prior art would lead one having ordinary skill in the art to expect such results, the unexpected results obtained by the presently claimed invention would rebut a *prima facie* showing of obviousness, even were such a showing established.

The Zeyuan reference cited by the Examiner actually further supports the unexpected effects of the presently claimed invention. This reference shows that black tea had a relatively moderate level of TG-lowering effect, while the corresponding green tea had a significantly greater TG-lowering effect. As described in Reference Document 2 attached to Applicants' previous response, the fermentation process involved in producing black tea from green tea substantially eliminates methyl catechins from the tea. Absent Applicants' discovery that teas high in methyl catechins produce an unexpectedly high level of TG-reduction, nothing in the Zeyuan reference would lead one having ordinary skill in the art to believe that the difference in TG-lowering effect results from differences in levels of methyl catechins. Thus, the difference in TG-lowering effects between the black tea and the green tea shown in the Zeyuan reference supports the unexpected results observed by Applicants.

b. The Combination of References Does Not Suggest the Claimed Invention

The two primary references, Zeyuan et al. and Xia, do not disclose or suggest methylated catechins. Zeyuan et al. teach that black tea lowers TG levels. Xia discloses that oolong tea, in

combination with a number of other ingredients, can be used to lower TG levels. However, nothing in Zeyuan et al. or Xia suggests that green teas high in methylated catechins, including the tea varieties recited in the present claims should be selected, or that there is any specific relationship between the ingredient contained in oolong tea and the effect of reducing blood triglyceride levels. Moreover, according to Chemistry and Function of Green tea, Black Tea, and Oolong Tea, Kougaku Shuppan, 1991, p. 27 (enclosed herewith, along with a partial English translation), the content of catechins found in fermented tea leaves of oolong tea is 45 to 70% less than in green teas. In view of this disclosure, the presently claimed catechins would be expected to exist only in trace amounts in the oolong teas disclosed by Xia et al.

Suzuki et al. disclose that a methylated catechin extract obtained from Benihomare and tong ting tea leaves has an anti-allergy effect. However, this reference does not teach or suggest that such an extract has any effect whatsoever on TG levels. Iwasaki et al. teaches an amount of catechin contained in oolong tea, but does not disclose anything about effective amounts of methylated catechins for reducing triglyceride levels. In addition, since the type and content of methylated catechins is different for each variety of tea recited in claim 1, the effect of reducing triglyceride levels in a beverage in Iwasaki et al. is determined based on the type of tea leaf consumed. In fact, in view of the teaching of the enclosed reference, the oolong tea disclosed by Iwasaki et al would not be expected to lower triglyceride levels since it contains only trace amounts of catechins.

In the absence of the inventors' teachings, one having ordinary skill in the art would not have any reason to select the particular varieties recited in the present claims out of all the many varieties of tea, because such a person would not know to select the varieties that have high levels of methyl catechins. It is only based on the disclosure of the present application that one of ordinary skill in the art would know to select specific varieties of tea, i.e. those with high levels of the recited methylated catechins, for the unexpected result of lowering TG levels. Thus, the claims cannot be obvious in view of the cited combination of references.

c. Conclusion of Nonobviousness

Even if the references had suggested the use of the recited methyl catechins derived from the recited varieties of tea for the reduction of TG levels, the unexpected results discussed above, would rebut any *prima facie* showing of obviousness raised thereby. Accordingly, in view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

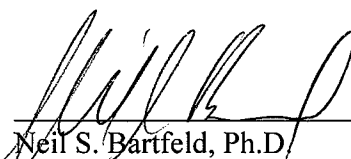
Applicants submit that all claims are in condition for allowance. However, if minor matters remain, the Examiner is invited to contact the undersigned at the telephone number provided below. If any additional fees are required, please charge these to Deposit Account No. 11-1410. Should there be any questions concerning this application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 7/31/09

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Chemistry and Function of Green Tea, Black Tea, and Oolong Tea, Kougaku Shuppan, p.27, (1991)

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- 20) 南条文雄, 原, 征彦, 万代隆彦, 渋谷 隆: 公報特許公報, 平成 7-179489 (1995).
- 21) 浅石修司, 神谷風太郎, 中川致之: 茶研報, 89, 29 (2000).
- 22) 広瀬真一, 正田重吉: 茶研報, 50, 51 (1979).
- 23) 中川致之: 茶葉分析研究, 58, 38 (1980).
- 24) 寺田志保子, 前田清美恵, 増井俊夫, 鈴木裕介, 伊藤和夫, 日食工業, 34, 20 (1987).
- 25) 矢松伸一, 久慈泰弘, 西郷英昭, 松田良子, 小松英樹: 食料工, 42, 419 (1995).
- 26) Goto, T., Yoshida, Y., Kiso, M., and Nagashima, H.: J. Chromatogr. A, 749, 295 (1996).

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IV. 烏龍茶の成分化学

烏龍茶は16世紀中頃から本格的に製造されていたと思われるが、世界に知られるようになったのは20世紀も半ば以降のようである。これは烏龍茶が中国の茶産生産量(30万トンの)の2~5%と低いことも理由の一つと考えられる。

烏龍茶の生産地は中国大陸福建省の武夷山地区(北閩地区, 武夷岩茶), 福州地区(閩南地区, 安溪烏龍茶, 例えば鉄観音, 黄金桂など日本人好みの茶), 広東地区, 台湾地区(台北地区, 台湾烏龍茶, 包種茶)の4地区に限られ, 台湾地区は大陸から製法が伝授されたと伝えられている。

近年, わが国では烏龍茶への嗜好が高まり, それにともなう化学的な研究成果も発表されるようになった。

高柳ら¹⁾は1979, 1980年に製造された台湾烏龍茶と包種茶のカテキン類を分析しているが, 発酵によるカテキン類の減少率は緑茶に対して烏龍茶では約45~70%, 包種茶では25%であって, 包種茶では発酵が軽度であることが理解される。津志田ら²⁾は各種茶のVitamin Cを測定し, 煎茶100に対し, 包種茶51, 烏龍茶16, 紅茶0の相対比を発表している。これらの結果からも包種茶, 烏龍茶の発酵の度合いを知ることができる。その他, 中国茶の一般成分, 遊離アミノ酸などを分析した將裕ら³⁾の報告もある。

1. カテキン類と関連化合物

(1) カテキン類と誘導体

烏龍茶カテキン類の研究が本格化したのは Hashimoto ら⁴⁾によるものである。中国福建省産の烏龍茶(市販名: 白折)の20%アセトン溶液で抽出した成分を Sephadex LH-20, MCI gel 等のクロマトグラフを組み合わせカテキン類の分離を行った(図IV-1)。

分離された主要なカテキン類およびその誘導体10致種類を図II-3に示した。烏龍茶に特有な成分は含まれないが, (-)-EC 3-O-4'-MeG, (-)-EGC 3-O-4'-MeG, (-)-EC 3-O-p-OH ben および(-)-EGC 3-O-cin などと比較的多く含まれる成分のようである。

- 20) 陳金文, 陳 征, 萬代園, 陳谷 隆: 公開特許公報, 平成 7-179489 (1995).
- 21) 坂石啓司, 神谷夏太郎, 中川致之: 茶研報, 89, 29 (2000).
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- 25) 茶松伸一, 久遠義弘, 西澤英昭, 松田良子, 小松美穂: 食料工, 42, 419 (1995).
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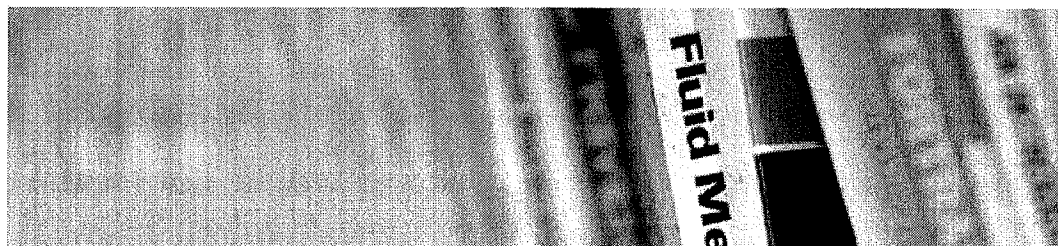
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IV. COMPONENT CHEMISTRY OF OOLONG TEA

Takayanagi et al.¹ analyzed catechins contained in Taiwanese oolong tea and pouchong teas, manufactured in 1979 and 1980, and found that oolong teas, when fermented, have a catechin content of 45 to 70% less than that of green teas, and pouchong teas, when fermented, have a catechin content of 25% less than that of green teas, suggesting that pouchong teas are fermented mildly.

**Titre du document / Document title**

Phenolic compounds of barley grain and their implication in food product discoloration

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Résumé / Abstract

Barley grains contain significant amounts of phenolic compounds that may play a major role in the discoloration of food products. Phenolic acid and proanthocyanidin (PA) composition of 11 barley genotypes were determined, using high-performance liquid chromatography and liquid chromatography-mass spectrometry, and their significance on food discoloration was evaluated. Abraded grains contained 146-410 µg/g of phenolic acids (caffeic, p-coumaric, and ferulic) in hulled barley and 182-282 µg/g in hullless barley. Hulled PA-containing and PA-free genotypes had comparable phenolic acid contents. Catechin and six major barley PAs, including dimeric prodelphinidin B3 and procyanidin B3, and four trimers were quantified. PAs were quantified as catechin equivalents (CE). The catechin content was higher in hullless (48-71 µg/g) than in hulled (32-37 µg/g) genotypes. The total PA content of abraded barley grains ranged from 169 to 395 µg CE/g in PA-containing hulled and hullless genotypes. Major PAs were prodelphinidin B3 (39-109 µg CE/g) and procyanidin B3 (40-99 µg CE/g). The contents of trimeric PAs including procyanidin C2 ranged from 53 to 151 µg CE/g. Discoloration of barley flour dough correlated with the catechin content of abraded grains ($r = -0.932$, $P < 0.001$), but not with the content of individual phenolic acids and PAs. Discoloration of barley flour dough was, however, intensified when total PA extracts and catechin or dimeric PA fractions were added into PA-free barley flour. The brightness of dough also decreased when the total PA extract or trimeric PA fraction was added into heat-treated PA-free barley flour. Despite its low concentration, catechin appears to exert the largest influence on the discoloration of barley flour dough among phenolic compounds.

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Mots-clés d'auteur / Author Keywords

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